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II

Calendar No. 128

103D CONGRESS
1ST SESSION

S. 298

[Report No. 103-82]

To amend title 35, United States Code, with respect to patents on certain processes.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 3 (legislative day, JANUARY 5), 1993

Mr. DECONCINI (for himself, Mr. HATCH, Mr. HEFLIN, Mr. KENNEDY, Mr. KOHL, Mr. LAUTENBERG, Mr. SPECTER, Mr. GRASSLEY, Mr. BROWN, Mr. DOMENICI, and Mrs. FEINSTEIN) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

JULY 1 (legislative day, JUNE 30), 1993

Reported by Mr. BIDEN, without amendment

A BILL

To amend title 35, United States Code, with respect to patents on certain processes.

- 1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **TITLE I—BIOTECHNOLOGICAL**
2 **PROCESS PATENTS**

3 **SEC. 101. CONDITIONS FOR PATENTABILITY; NONOBVIOUS**
4 **SUBJECT MATTER.**

5 Section 103 of title 35, United States Code, is
6 amended—

7 (1) in the first unnumbered paragraph by in-
8 serting “(a)” before “A patent”;

9 (2) in the second unnumbered paragraph by in-
10 serting “(b)” before “Subject matter”; and

11 (3) by adding at the end thereof the following
12 new subsections:

13 “(c) Notwithstanding any other provision of this sec-
14 tion, a claimed process of making or using a machine,
15 manufacture, or composition of matter is not obvious
16 under this section if—

17 “(1) the machine, manufacture, or composition
18 of matter is novel under section 102 of this title and
19 nonobvious under this section;

20 “(2) the claimed process is a biotechnological
21 process as defined in subsection (d); and

22 “(3)(A) the machine, manufacture, or composi-
23 tion of matter, and the claimed process invention at
24 the time it was made, were owned by the same per-

son or subject to an obligation of assignment to the same person; and

“(B) claims to the process and to the machine, manufacture, or composition of matter—

“(i) are entitled to the same effective filing date; and

“(ii) appear in the same patent application, different patent applications, or patent which is owned by the same person and which expires or is set to expire on the same date.

“(d) For purposes of this section, the term ‘biotechnological process’ means any method of making or using living organisms, or parts thereof, for the purpose of making or modifying products. Such term includes recombinant DNA, recombinant RNA, cell fusion including hybridoma techniques, and other processes involving site specific manipulation of genetic material.”.

SEC. 102. NO PRESUMPTION OF INVALIDITY.

The first unnumbered paragraph of section 282 of title 35, United States Code, is amended by inserting after the second sentence “A claim issued under the provisions of section 103(c) of this title on a process of making or using a machine, manufacture, or composition of matter shall not be held invalid under section 103 of this title solely because the machine, manufacture, or composition

1 of matter is determined to lack novelty under section 102
2 of this title or to be obvious under section 103 of this
3 title.”.

4 **SEC. 103. EFFECTIVE DATE.**

5 The amendments made by this title shall apply to all
6 United States patents granted on or after the date of the
7 enactment of this Act and to all applications for United
8 States patents pending on or filed after such date of enact-
9 ment, including any application for the reissuance of a
10 patent.

11 **TITLE II—BIOTECHNOLOGICAL**
12 **MATERIAL PATENTS**

13 **SEC. 201. INFRINGEMENT BY IMPORTATION, SALE OR USE.**

14 (a) INFRINGEMENT.—Section 271 of title 35, United
15 States Code, is amended by adding at the end the follow-
16 ing new subsection:

17 “(h) Whoever without authority imports into the
18 United States or sells or uses within the United States
19 a product which is made by using a biotechnological mate-
20 rial (as defined under section 154(b)) which is patented
21 in the United States shall be liable as an infringer if the
22 importation, sale, or use of the product occurs during the
23 term of such patent.”.

24 (b) CONTENTS AND TERM PATENT.—Section 154 of
25 title 35, United States Code, is amended—

1 (1) by inserting “(a)” before “Every”;
2 (2) by striking out “in this title,” and inserting
3 in lieu thereof “in this title (1)”;
4 (3) by striking out “and, if the invention” and
5 inserting “(2) if the invention”;
6 (4) by inserting after “products made by that
7 process,” the following: “and (3) if the invention is
8 a biotechnological material used in making a prod-
9 uct, of the right to exclude others from using or sell-
10 ing throughout the United States, or importing into
11 the United States the product made or using such
12 biotechnological material,”; and
13 (5) by adding at the end thereof the following:
14 “(b) For purposes of this section, the term
15 ‘biotechnological material’ is defined as any material (in-
16 cluding a host cell, DNA sequence, or vector) that is used
17 in a biotechnological process as defined under section
18 103(d).”.

19 (c) EFFECTIVE DATE.—

20 (1) IN GENERAL.—The amendment made by
21 this section shall take effect six months after the
22 date of enactment of this Act and, subject to para-
23 graph (2), shall apply only with respect to products
24 made or imported after the effective date of the
25 amendments made by this section.

1 (2) EXCEPTIONS.—The amendments made by
2 this section shall not abridge or affect the right of
3 any person, or any successor to the business of such
4 person—

5 (A) to continue to use, sell, or import
6 products in substantial and continuous sale or
7 use by such person in the United States on the
8 date of enactment of this Act; or

9 (B) to continue to use, sell, or import
10 products for which substantial preparation by
11 such person for such sale or use was made be-
12 fore such date, to the extent equitable for the
13 protection of commercial investment made or
14 business commenced in the United States be-
15 fore such date.

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